UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,628	03/09/2001	William J. Curatolo	PC8626CMAS	7884

7590 10/06/2003

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	13

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/803,628	Applicant(s) CURATOLO ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE filed April 14, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *149-190 and 208-214* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *149-190 and 208-214* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 149-190 and 208-214 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 14, 2003 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 14, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Allowable Subject Matter

3. The indicated allowability of claims 149-190 and 208-214 is withdrawn in view of the newly discovered reference(s) to Curatolo et al. (US 5,605,889) in view of Morishita et al. (Drug Design and Delivery, 1991). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 149-190 and 208-214 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (US 5,605,889) in view of Morishita et al. (Drug Design and Delivery, 1991).

Curatolo et al. teaches a dosage form of azithromycin which can be administered to a mammal. The azithromycin can be in various forms such as a pharmaceutically acceptable salt, anhydrous or hydrous, or as a dihydrate and are formulated from about 25 mg to about 3 grams (col. 4, lines 51-61). Column 2, lines 45-54 teach that the composition can be administered as a tablet or in unit dosage packets "sachet" comprising the azithromycin and a pharmaceutically acceptable carrier. Column 6, lines 62-67 teach the use of binders such as cellulose derivatives. It is taught in column 8, lines 19-27 that the drug could be formulated into a powder for the purposes of making oral suspensions. Column 7, lines 61-64 teach that a coating can be employed. The prior art does not teach the dosage form being delivered to the gastrointestinal tract as claimed. It is also not taught the dosage form comprising a plurality of microparticles.

Morishita et al. teaches controlled-release preparations such as enteric-coated and sustained releases preparations which are designed to enable a drug release at a

limited segment or though the whole region of the gastrointestinal tract (introduction). The preferred enteric-coated is Eudragit L100, a pH-dependent copolymer.

It is the object of the present application to release the drug in a portion of the gastrointestinal tract distal to the duodenum to avoid gastrointestinal side effects. It would therefore be obvious to one of ordinary skill in the art to use the coatings of Morishita which teaches that the coatings are designed to release the preferred amount of drug at a limited segment or through the whole region of the gastrointestinal tract with the preparations of Curatolo. The expected result would be an oral dosage form that releases a specific amount of drug in a specific region i.e. distal to the duodenum and that would aid to avoid gastrointestinal side effects. It would also have been obvious to one of ordinary skill in the art to formulate the dosage form containing a plurality of particles for the purposes of controlling the drug release rate.

Conclusion

5. Claims 149-190 and 208-214 stand rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George
Patent Examiner
Art Unit 1616